# NeuroTrac™ IFC Rehab

*IFC Stimulator / Dual channel TENS&NMS Stimulator*
*Three product in one!*

**OPERATION MANUAL**

ENG

VERITY MEDICAL LTD

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# 1. Contra indications Precautions and Warnings

Please read the following prescription information carefully before using your NeuroTrac™ IFC Rehab. If you have any questions regarding this information, consult with your physician or therapist before proceeding.

## Contra indications:

Do not use NeuroTrac™ IFC Rehab:

- With demand type cardiac pacemakers
- Over the carotid sinuses (neck) region,
- Transcerebrally ( over the head),
- Over the eyes,
- Whenever pain syndromes are undiagnosed, until the etiology has been established ,
- When there is a tendency to hemorrhage following acute trauma or fracture,
- Following recent surgical procedures when muscle contraction may disrupt the healing process,
- Over areas of skin which lack normal sensation,
- On cancer patients.

## Warnings:

- The NeuroTrac™ IFC Rehab mast be used with the guidance of a Clinician or Therapist.
- The long-term effects of continuous electrical stimulation are unknown.
- Safety during pregnancy, labour and delivery has not been established for either mother or foetus.
- The NeuroTrac™ IFC Rehab is not effective in treating pain of central origin, including headache.
- The NeuroTrac™ IFC Rehab in TENS or IFC mode provides symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
- Adequate precautions should be taken in the case of persons with suspected heart problems.
- Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.

- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
- Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Patient Electrodes are for single patient use only!
- Do not use stimulation on your facial area unless you are under strict guidance from a qualified clinician.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contraction may be strong enough to close the airway or cause difficulty breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when NeuroTrac™ IFC Rehab stimulation is in use.
- Do not immerse unit into water or any other substance.
- Do not insert lead wires into mains power supply
- Do not use the NeuroTrac™ IFC Rehab in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide.
- If using rechargeable AA Nickel Metal Hydride batteries be sure to use CE marked battery charger. We recommend not to use Ni-Cad type rechargeable batteries.
- Never connect the NeuroTrac™ IFC Rehab directly to a battery charger any other mains powered equipment.
- No modification of this equipment is allowed!

## Precautions:

- Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application. Consult your physician if skin irritation develops.
- The effectiveness of NeuroTrac™ IFC Rehab in TENS mode is highly dependent upon programme selection by a person qualified in the management of pain patients.
- Caution should be used in the presence of the following:
  - When there is a tendency to hemorrhage following acute trauma or fracture
  - Following recent surgical procedures when muscle contraction may disrupt the healing process
  - Over the menstruating or pregnant uterus
  - Over areas of the skin which lack normal sensation
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium or an alternate electrode placement
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner
- Powered muscle stimulators should be kept out of the reach of children
- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer
- Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury

## Adverse Reactions:

- Skin irritation and electrode burns are potential adverse reactions.

# 2. Introduction to the product

NeuroTrac™ IFC Rehab is a pain control and muscle stimulator device. It combines Interferential stimulator (IFC), Transcutaneous Electrical Nerve Stimulator (TENS) and Neuromuscular Electrical stimulator (NMS) in one unit. The device consists of two independent circuits, one for IFC, another for TENS/NMS stimulation. There are two output Channels for the NMS and another two for the IFC allowing it to operate 2 pairs of electrodes for each side of the device. They are all isolated from each other and work independently with no exchange of current between any of the channels.

IFC Rehab has 11 built- in preset programmes for Interferential stimulation , 12 for TENS stimulation and 15 for NMS stimulation. Additionally there are custom programmes ( 2 for IFC, 2 for NMS and 1 for TENS) which allow to vary programme parameters.

Each of two parts of the device ( IFC or TENS/NMS) can be locked separately by Physician to prevent patient from changing programme parameters and to allow verification of the training by collecting "total time used" and average output amplitude statistic.

## 2.1. What is Pain

When we feel pain it is the body's process of informing us that something is wrong. To feel pain is important, without this feeling abnormal conditions may go undetected, creating damage or injury to critical parts of the body.

Although pain is essential in warning our body of trauma or malfunction, nature may have gone too far in its design. Continued long-term chronic pain has no useful value apart from its importance in diagnosis. Pain only begins when a coded signal travels to the brain where it is decoded, and analysed. The pain message travels from the injured area of the body along small diameter nerves leading to the spinal cord. At this point the message is switched to a different kind of nerve that travels up the spinal cord to the brain area. The brain then analysis the pain message, refers it back and the pain is felt.

## 2.2. What is TENS

Transcutaneous Electrical Nerve Stimulation (TENS) is a non-invasive method of controlling acute and principally long term intractable pain. It can also be used as an adjunctive treatment in the management of post surgical traumatic pain problems. In TENS mild electrical impulses are transmuted through the skin via surface electrodes to modify the body's pain perception. TENS does not cure problematic physiological conditions; it only helps to control the pain perception. TENS will not work for every user. However Physical Therapists and Physicians throughout the world prescribe TENS extensively and it is generally seen to work for the majority of users. There are millions of small nerve fibres throughout the body and it only requires a few impulses to produce chronic pain. In addition to small fibres, which allow the sensation of pain to be felt, the body is also made up of larger diameter nerve fibres.

These larger nerve fibres transmit less unpleasant sensations such as touch or warmth, assisting us to form an impression of our environment.
Stimulating the larger nerve fibres using TENS may have the effect of inhibiting the transmission of pain along the smaller nerve fibres to the spinal cord (this effect is known as the '*Pain Gate Theory*').

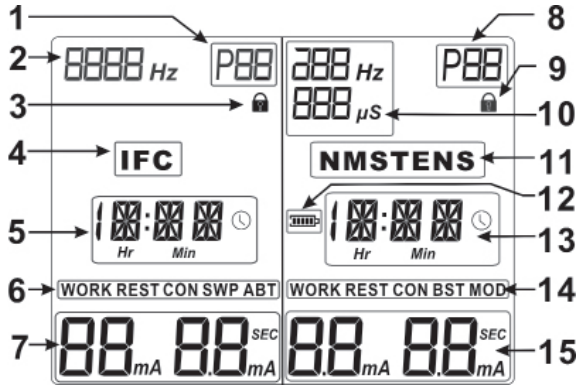
## 2.3. What is NMS (NMES)

Neuromuscular Electrical Stimulation is the elicitation of muscle contraction using electric impulses. The impulses are generated by a device and delivered through electrodes on the skin in direct proximity to the muscles to be stimulated. The impulses mimic the action potential coming from the central nervous system, causing the muscles to contract. It is commonly used as a therapeutic intervention for muscle strengthening. It can be used to augment the strength of either injured or healthy muscle. Generally it is used on the superficial muscles of the arms and shoulder gridle, the legs, and low back. An isolated injury with specific muscular strength deficits , such as quadriceps weakness or lumbar para spinal weakness , is the most common impairment that is treated with NMS for strengthening.

## 2.4. What is Interferential Stimulation (IFC)

Interferential stimulation differs from conventional neuromascular stimulation (NMS) and transcutaneous electrical nerve stimulation (TENS). Both TENS and NMS uses discrete electric impulses delivered at low frequencies of 2-200 pulses per second which deliver most stimulation to the surface of the skin directly under the electrode.
Interferential stimulation depends upon the interaction or interference of two medium-frequency electrical outputs that differ slightly in frequency. In other words , the current that would be produced by one channel interacts with (*interferes with*) the current produced by second channel and produces a net ionic movement different from that produced by either channel alone. Such resultant current (called *interference current*) has a frequency that is equal to the difference in frequency of on the two channels. Since the frequencies of interferential stimulation are much higher than those used in TENS and NMS the tissue impedance is reduced and the currents are induced in deeper tissue level.
NeuroTrac™ IFC Rehab uses a fixed carried frequency of 4000Hz and an pre set or adjustable frequency in a range: 4001 - 4150Hz. When the two frequencies mix inside the tissue they interfere , producing an interference frequency.

# 3. Description of display




**IFC side**

1. Programme number
2. Frequency
3. Lock status indication
4. Mode indiction
5. Programme timer
6. Modality indication
7. Channel 1, 2 mA level

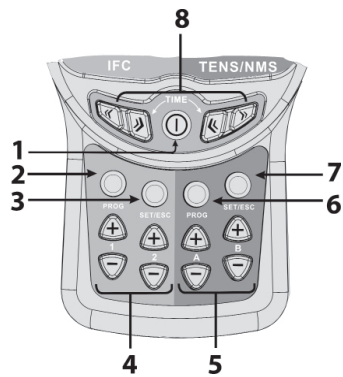
**TENS/NMS side**

8. Programme number
9. Lock status indication
10. Programme Hz, uS
11. Mode indication
12. Battery Level indication
13. Programme timer
14. Modality indication
15. Channel A, B mA level

# 4. Description of Controls

1. **ON/OFF button**.
   Switches the unit on and off.

2. **IFC Prog button**
   Scrolls through IFC programmes *(P01-P11 for predefined programmes PC1and PC2 for custom programmes).*



**3. IFC SET/ESC Button**:

a). *SET function* (home screen of custom programme). Pressed and hold for 3 seconds enables to enter custom programme set up menu .

b). *ESC function:* while programme is running pressed one time pauses the programme, reduces mA level to 0 and freezes the clock, pressed second time returns to home screen; while in custom programme settings menu saves the settings and returns to home screen.

**4. IFC intensity buttons (Ch1+/- and Ch2+/-)**

Start the programme and increase (or decreases) mA level. In custom programme set up menu Ch1 buttons for parameter selection and Ch2 buttons for parameter value adjustment.

**5. TENS/NMS intensity buttons (ChA+/- and ChA+/-)**

Start the programme and increases ( or decreases) mA level. In custom programme set up menu ChA buttons for parameter selection and ChB buttons for parameter value adjustment.

**6. TENS/NMS SET/ESC Button**

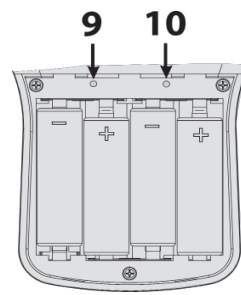
a). *SET function* (home screen of custom programme). Press and hold for 3 seconds to enter the custom programme set up menu .

b). *ESC function:* while programme is running press once to pause the programme , it reduces mA level to 0 and freezes the clock. Press again to return to the home screen. If in custom programme settings menu and ESC is pressed, it saves the settings and returns to the home screen.

**7. TENS/NMS Prog button**

Scrolls through TENS/NMS programmes

*(P01-P11 for TENS programmes ,P13-P27 for NMS programmes , PC1 for custom TENS ,PC2 and PC3 for custom NMS programmes)* .




**8. Timer buttons**

Programme time adjustment.

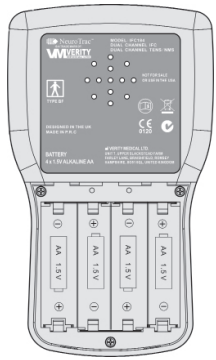
**9. TENS/NMS lock button**.

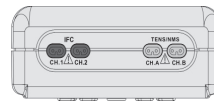
**10. IFC lock button.**

# 5. Operating NeuroTrac™ IFC Rehab

## 5.1 Getting started

1. Insert four AA batteries into the battery compartment (the battery images engraved in the base of the compartment indicates correct battery position.




2. Connect the lead cables to the electrodes. The lead pins must be fully inserted into the electrode connector.
3. Place the electrodes on the sides prescribed by your physician or therapist, and press them firmly onto the skin (place the two electrode pairs that are controlled by the same amplitude buttons on muscles that are about the same size).
4. Insert the plugs at the end of the electrode lead cable into device output sockets : **CH1 and CH2 output sockets for IFC stimulation or CHA and CHB output sockets for TENS/NMS stimulation.**
5. Press **On/Off** button to switch the unit on. The unit always starts up with previously selected programme.
6. Press IFC PROG button or TENS/NMS programme button to select the programme:
   - **a)** **IFC PROG button**: P01 - P11 for preset programmes, PC1 or C2 for Custom programmes .
   - **b)** **TENS/NMS PROG button**: P01-P12 for preset TENS programmes, P13-P27 for preset NMS programmes, PC1 for TENS custom programme, PC1 or PC2 for NMS custom programmes.

7. When the programme is done amplitude automatically returns to 0
8. If required adjust the time of the programme by using timer button. Time of predefined IFC , TENS and NMS P13-P15 programmes can be adjusted in the range: 1min- 12hrs, ( **Note:** time of predefined NMS programmes P16 - P27 cannot be changed as these are multiphasic programmes).

**How long do I use TENS or IFC for?**
This depends on the individual patient's condition, accuracy of electrode placement, stimulation and the characteristics selected, but typically the onset of pain relief starts after 20 - 30 minutes. Generally TENS is used for longer periods of normally 1 hour 30 minutes per session. With some patients it can be much longer.

9. Start the stimulation by setting the desired amplitude using "**+** Plus" buttons. To reduce stimulation press the " **-** Minus" buttons.

   **Note:** Patients respond differently to the level of intensity, this is due to differences in individual patient's skin resistance, enervation and the type and condition of electrode being used.

10. You can always stop the programme by pressing ⏻

    To pause the programme press ESC button which will reduce mA to 0 and freeze programme time counter, pressing ESC again will return the programme to home screen.

**Intensity Lock Out Feature**

To prevent an accidental increase of the treatment amplitude (intensity), NeuroTrac™IFC Rehab has an Intensity Lock Out feature implemented. Once the stimulation current is raised above zero, with no buttons activity for greater than 10 seconds, the unit will lockout the Increase intensity **buttons (CH1+ and CH2+ for IFC or CHA+ and CHB+ for TENS/NMS).** To deactivate Intensity Lock out "- Minus" button needs to be pressed **.**

**Open Circuit Detect**

If the closed circuit is broken, for example if a lead wire is broken, or electrode does not provide proper contact with the skin the current of the channels switches off automatically which is indicated by the amplitude dropping to 0 mA and timer paused. To resume the treatment the problem needs to be corrected and programme restarted by setting the amplitude. The programme picks up where it left off.

# 5.2. Setting up IFC Custom programme.

## Continuous mode custom IFC programme (PC1)

1. Select **PC1** by pressing IFC PROG. button
2. Press and hold IFC SET/ESC button for 3 seconds to enter custom programme parameter adjustment menu
3. Flashing **Hz** symbol indicates that frequency can be adjusted. Use "**CH2 +"** or "**CH2 -"** to adjust frequency in range from 1 - 150 Hz ( 1 Hz step)
4. Once frequency is adjusted press SET/ESC button to save settings and return to Home screen

## Work/Rest mode IFC custom programme(PC2)

1. Select PC2 by pressing IFC PROG. button
2. Press and hold SET/ESC button for 3 seconds to enter custom programme parameter adjustment menu
3. Flashing **Hz** symbol indicates that frequency can be adjusted. Use "**CH2 +"** or "**CH2 -"** button to adjust frequency in range from 1 - 150 Hz ( 1 Hz step)
4. Press "**CH1**+" button to change to work time adjustment screen. Flashing **WORK** segment indicates that work period can be adjusted. Use "**CH2 +"** or "**CH2 -"** button to adjust the time in range from 1 - 99 seconds (1 sec. increments).
5. Press "**CH1**+" button again to change to rest time adjustment screen. Flashing **REST** segment indicates that rest period can be adjusted. Use "**CH2 +"** or "**CH2 -"** button to adjust the time in range from 1 - 99 seconds (1 sec. increments).
6. Press SET/ESC button to save settings and return to home screen.

   If "**CH1**+" button was pressed again rather than SET/ESC then the device would loop back to the Hz adjustment screen, similarly if "**CH1**-" button was pushed LCD would loop back to Work time setting screen.
7. Repeat above procedure to re-adjust custom programme.

# 5.3. Setting up TENS/NMS Custom programme.

## Custom TENS programme (PC1)

1. Select **PC1** by pressing TENS/NMS PROG. button
2. Press and hold TENS/NMS SET/ESC button for 3 seconds to enter custom programme parameter adjustment menu
3. Flashing **Hz** symbol indicates that frequency can be adjusted. Use " **CHB +"** or **CHB -** to adjust frequency in range from 2 - 200 Hz (selectable Hz values: 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 14, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, 100, 150 , 200)
4. Press "**CHA**+" button to change to Pulse Width adjustment screen. Flashing **µS** segment indicates that pulse width can be adjusted. Use "**CHB +"** or "**CHB -"** button to adjust the width in range from 50 - 300 µS. ( selectable µS values: 50, 75, 100, 125, 150, 175, 200, 220, 250, 275, 300)
5. Once Pulse width has been adjusted press SET/ESC button to save settings and return to Home screen.

   If "**CHA**+" or "**CHB** -" button was pressed again rather than SET/ESC then the device would loop back to the Hz adjustment screen .
6. Repeat above procedure to readjust custom programme.

## Custom NMS programme (PC2, PC3)

1. Select **PC2 or PC3** by pressing TENS/NMS PROG. button
2. Press and hold TENS/NMS SET/ESC button for 3 seconds to enter custom programme parameter adjustment menu.
3. Flashing **Hz** symbol indicates that frequency can be adjusted. Use " **CHB +"** or **CHB -** to adjust frequency in range from 2 - 100 Hz (selectable Hz values: 2, 3, 4, 5, 6, 7, 8 , 9, 10, 12, 14, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, 100 )
4. Press "**CHA**+" button to change to Pulse Width adjustment screen. Flashing **µS** segment indicates that pulse width can be adjusted. Use "**CHB +"** or "**CHB -"** button to adjust the width in range from 50 - 450 µS. ( selectable µS values: 50, 75, 100, 125, 150, 175, 200, 220, 250, 275, 300, 450 )

5. Press "**CHA**+" button again to change to work time adjustment screen. Flashing **WORK** segment indicates that work period can be adjusted. Use "**CHB +"** or "**CHB -"** button to adjust the time in range from 1 - 99 seconds (1 sec. increments).

6. Press "**CHA**+" button again to change to rest time adjustment screen. Flashing **REST** segment indicates that rest period can be adjusted. Use "**CHB +"** or "**CHB -"** button to adjust the time in range from 1 - 99 seconds (1 sec. increments).

7. Press "**CHA**+" button again to change to ramp up time adjustment screen. Flashing **RMP** segment indicates that ramp up time can be adjusted can be adjusted. Use "**CHB +"** or "**CHB -"** button to adjust the time in range 0.3 - 9.9 seconds ( 0.1 sec increments)

8. Press "**CHA**+" button again to change to ramp up time adjustment screen. Flashing **RMP** segment indicates that ramp up time can be adjusted can be adjusted. Use "**CHB +"** or "**CHB -"** button to adjust the time in range 0.3 - 9.9 seconds ( 0.1 sec increments)

9. Press "**CHA**+" button again to change to output SYN/ALT selection screen (synchronous or alternating) . Flashing **SYN (or ALT)** symbol indicates that output type can be set to synchronous (SYN) or alternating (ALT). Use "**CHB +"** or "**CHB -"** button to select SYN or ALT.

   **Synchronous (SYN)** means that both Channel A and Channel B will give output at the same time of each Work period.

   **Alternating (ALT)** means that Channel A will work while Channel B will be off for one Work period and then for the next Work period Channel B will be on while but Channel A will be off and so on until the end of the programme time.

10. If SYN (Synchronous) has been selected, press the "**CHA**+" button again to change to delay time adjustment screen. Flashing **DLY** symbol indicates that delay time of channel B can be adjusted. Use "**CHB +"** or "**CHB -"** button to set required time in range 0 - 4 seconds ( 0.1 sec increments).

11. Once delay ( or output synchronization) has been adjusted press SET/ESC button to save settings and return to Home screen.

    If "**CHA**+" or "**CHB** -" button was pressed again rather than SET/ESC then the device would loop back to the Hz adjustment screen .

12. Repeat above procedure to readjust custom programme.

# 5.4. IFC programme table and modes

| | Prog No. | MODE | Interferential Frequency | Dwell , modulation or W/R time | Prog. |
|---|---|---|---|---|---|
| **IFC** predefined | P01 | ABT | | | 1min -12h |
| | P02 | ABT | | | |
| | P03 | ABT | | | |
| | P04 | SWP | | | |
| | P05 | SWP | | | |
| | P06 | ABT | | | |
| | | SWP | | | |
| | P07 | ABT | | | |
| | | SWP | | | |
| | P08 | WORK/REST | | | |
| | P09 | WORK/REST | | | |
| | P10 | WORK/REST | | | |
| | | CON | | | |
| | P11 | CON | | | |
| | | WORK/REST | | | |
| **IFC** Custom | PC1 | CON | | - | |
| | PC2 | WORK/REST | | | |

Description of IFC modes:

**1**. **Abrupt (ABT)**

Output with low frequency for a set dwell time and then abrupt change to high frequency for the same dwell time. Cycle is repeated over programme duration

**2**. **Ramp (SWP)**

Stimulation frequency ramps smoothly from low frequency to high frequency for a defined modulation time , then back . Cycle is repeated over programme duration

**3**. **Intermittent stimulation** (**WORK/REST)**

Intermittent stimulation where output amplitude ramps up in 0.5 sec. to adjusted level and stimulates for a defined **WORK** time , then it ramps down in 0.5 sec. to 0 mA, and stays with no stimulation for a defined **REST** time. Cycle is repeated over programme duration.

**4. Continuous (CON)**

Train of constant value pulses on both channels delivered with no interruption for entire treatment period

**5. Dual Treatment ( ABT / SWP, WORK/REST / CON)**

In Programme P06, P07, P10, P11 two modes are combined together into one programme. Each mode lasts for ½ of the defined total programme time. When changing from one mode to another the amplitude is reduced 50 % and needs to be readjusted by patient to desired level.

# 5.5. TENS/NMS programme tables and modes

| | Prog No. | Mode | Frequency (Hz) | Pulse Width (µS) | Prog. Time |
|---|---|---|---|---|---|
| **TENS** predefined | P01 | CON | | | 1min -12h |
| | P02 | CON | | | |
| | P03 | BST | | | |
| | P04 | MOD | | | |
| | P05 | CON | | | |
| | P06 | CON | | | |
| | P07 | CON | | | |
| | P08 | CON | | | |
| | P09 | CON | | | |
| | P10 | CON | | | |
| | P11 | MOD | | | |
| | P12 | BST | | | |
| **NMS** predefined | P13 | NMS | | | 1min-1.5h |
| | P14 | NMS | | | |
| | P15 | NMS | | | |
| | P16 | NMS | | | 50min |
| | P17 | NMS | | | 40min |
| | P18 | NMS | | | 37min |
| | P19 | NMS | | | 35min |
| | P20 | NMS | | | 35min |
| | P21 | NMS | | | 25min |
| | P22 | NMS | | | 50min |
| | P23 | NMS | | | 30min |
| | P24 | NMS | | | 35min |
| | P25 | NMS | | | 50min |
| | P26 | NMS | | | 15min |
| | P27 | NMS | | | 55min |
| **CUSTOM** | PC1 Custom | CON | | | 1min -12h |
| | PC2 Custom | NMS | | | 1min-1.5h |
| | PC3 Custom | NMS | | | |

Description of TENS/NMS modes

**1. Continuous /Conventional TENS (CON)**

Continuous train of constant value pulses (fixed frequency and pulse duration) on both channels delivered with no interruption for entire treatment period.

**2. Burst Modulated TENS (BST)**

Regular burst of pulses ( nine pulses of 200µS or 175 µS at 150Hz) repeated 2 times per second .This mode is comparable to the low rate TENS technique except that each low rate pulse is substituted for by a short BURST of pulses. It is a combination of conventional and low rate TENS.

**3. Modulated TENS**

Systematic modulation( lowering from and rising to the maximum settings) of the pulse duration and pulse frequency . This mode was designed to help prevent nerve accommodation that some patient's experience. It is achieved by continuously cycling the pulse width and rate.
Modulation is exponential. For example: Modulation time 6 seconds, 50-250 µS means starting at 50 µS increasing exponentially (fast then slow) to 250 µS in 3 seconds and returning (fast then slow) back to 50 µS to complete the cycle in 6 seconds.

**4. NMS (Neuromuscular Electrical Stimulation)**

Intermittent stimulation where output amplitude ramps up in to adjusted level and stimulates for a defined **WORK** time , then it ramps down to 0 mA, and stays with no stimulation for a defined **REST** time. Cycle is repeated over programme duration.

| **Programme : P13** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 6 | | | | |
| Mode | | CON | | | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | secs | | | | | |
| Ramp down time | secs | | | | | |
| Work time | secs | | | | | |
| Rest time | secs | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | | | | |
| Overall time | 6 min | | | | | |

| **Programme: P14** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 20 | | | | |
| Mode | | CON | | | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | secs | | | | | |
| Ramp down time | secs | | | | | |
| Work time | secs | | | | | |
| Rest time | secs | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | | | | |
| Overall time | 20 min | | | | | |

| **Programme: P15** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 50 | | | | |
| Mode | | W/R | | | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | | | | |
| Overall time | 50 min | | | | | |

| **Programme: P16** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 12 | 7 | 10 | 16 |
| Mode | | CON | W/R | CON | W/R | CON |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | √ | √ |
| Overall time | 50 min | | | | | |

| **Programme: P17** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 12 | 5 | 12 | 6 |
| Mode | | CON | MF | CON | MF | CON |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Modulation Time | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | √ | √ |
| Overall time | 40 min | | | | | |

| **Programme: P18** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 10 | 10 | 12 | |
| Mode | | CON | MF | MF | CON | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Modulation Time | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | √ | |
| Overall time | 37 min | | | | | |

| **Programme: P19** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 20 | 10 | | |
| Mode | | CON | W/R | CON | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | | |
| Overall time | 35 min | | | | | |

| **Programme: P20** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 15 | 15 | | |
| Mode | | Cont | W/R | Cont | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | | |
| Overall time | 35 min | | | | | |

| **Programme: P21** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 5 | 5 | 5 | 5 |
| Mode | | CON | W/R | CON | W/R | CON |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Modulation time | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | √ | √ |
| Overall time | 25 min | | | | | |

| **Programme: P22** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 20 | 20 | 10 | | |
| Mode | | MF | MF | W/R | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Modulation time | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | | |
| Overall time | 50 min | | | | | |

| **Programme: P23** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 15 | 10 | | |
| Mode | | CON | W/R | CON | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | | |
| Overall time | 30 min | | | | | |

| **Programme: P24** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | mins | 10 | 25 | | | |
| Mode | | CON | CON | | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Modulated time | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | | | |
| Overall time | 35 min | | | | | |

| **Programme: P25** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 15 | 10 | 15 | 5 |
| Mode | | CON | W/R | W/R | W/R | CON |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | √ | √ |
| Overall time | 50 min | | | | | |

| **Programme: P26** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 5 | 3 | 3 | 2 | 2 |
| Mode | | CON | W/R | W/R | W/R | W/R |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | √ | √ |
| Overall time | 15 min | | | | | |

| **Programme: P27** | | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---|---|---|---|---|---|---|
| Phase time | min | 25 | 20 | 10 | | |
| Mode | | CON | CON | CON | | |
| Frequency work | | | | | | |
| Frequency rest | | | | | | |
| Pulse duration | | | | | | |
| Modulation time | | | | | | |
| Ramp up time | | | | | | |
| Ramp down time | | | | | | |
| Work time | | | | | | |
| Rest time | | | | | | |
| Alternating | | | | | | |
| Synchronous | | √ | √ | √ | | |
| Overall time | 55 min | | | | | |

# 5.6. Lock Mode function

A "concealed" Lock buttons are included in the NeuroTrac™ IFC Rehab, which allows the Physician to accurately monitor the "Home Compliance" of the patient between appointments. The lock function allows the device to be locked in two ways (**Note:** IFC side and TENS/NMS side have lock button therefore can be locked independently).

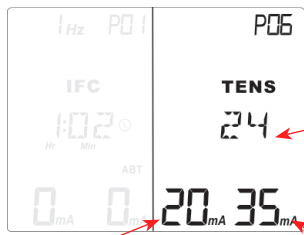
1. **L: T** - to measure the time in use (over one hour), and the average mA current used, leaving the programmes and its parameters to be freely altered by the user.
2. **L: PT** - to measure, time in use ( over one hour) , mA current used and locking the programme and parameters in place, which then cannot be changed or altered by the patient during use.

## Locking the unit.

The Lock buttons will only respond in the "Home" screen. That is when a programme has been selected and set up ready to start.
Remove the battery cover and, using pin ( i.e lead wire pin) gently press on the concealed lock button until you hear a double bleep. **L: T** will appear on the LCD screen. If you want to lock the parameters as well press the CH2+/- buttons ( for IFC side) or CHB+/- buttons ( for TENS/NMS side) until **L: PT** appears. Press the SET/ESC button to save lock setting and return to home screen. Once device is locked symbol appears on LCD.

## Unlocking the unit.

To unlock the unit and display the lock information, remove the battery cover, using the pin press the concealed switch once and you will hear a single bleep, this indicates the unit is now unlocked. The information for time in use and the average m A current used can be read on the front of the LCD display as seen on the picture below (unlock screen for TENS P06). Once the information is noted press the SET/ESC button to bring the unit back to the Home position.



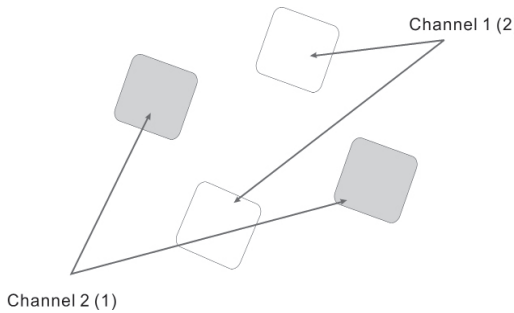
# 6. Skin Electrodes( Self- adhesive electrodes)

## Electrode placement

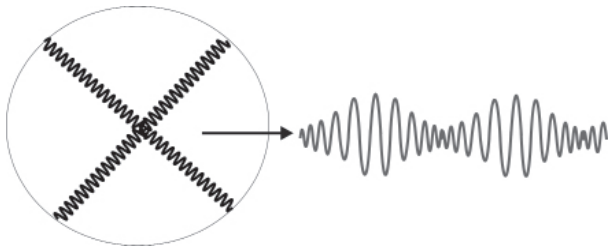
The placement of electrodes is one of the most important parameters in achieving effective pain relief using TENS. This is best left to your Physiotherapist or Physician to advise as to which location is most appropriate.

**Quadripolar orientation of electordes for IFC stimulation.**

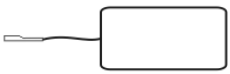
True interferential stimulation requires the use of four electrodes placed on the body as described in the diagram below. Each pair of electrodes creates a current flow between them. When two pairs of electrodes are used, the current flows intersect within the tissue. By making the frequencies for the two channels of stimulation slightly different, an interference or "beat" frequency is established at the point of intersection. This "quadrapolar" interferential effect provides a greater amount of stimulation deeper within the tissue than non-interferential modes of electrotherapy.




A conceptual drawing of quadripolar ( 4 electrodes) stimulation with interference taking place within tissue



## Avaliable types of electordes

| Shape | Code | Description |
|---|---|---|
| | VS.4040 | 40 x 40 mm, square (* max 53mA) |
| | VS.5050 | 50 x 50 mm, square (recommended for general use) |
| | VS.9040 | 90 x 40 mm, rectangular |
| | VS.9050 | 90 x 50 mm, rectangular |
|  | VS.10050 | 100 x 50 mm, rectangular |
| | VS.30 | 30 mm diameter, round (* max 46mA) |
| | VS.50 | 50 mm diameter, round |
| * IMPORTANT : Don't use VS 4040 at more than 53mA and VS3030 at more than 46 mA. | | |

## Practical tips

- If you find the electrodes will not stick due to oily skin, cleanse the skin with soap and water, then rinse and dry the area around the electrode site. If this does not work, try cleansing the skin with a swab impregnated with alcohol.
- Clip away hairy skin using scissors; don't use a razor to remove the hairs!
- The electrodes conductive material is water- based. If it becomes saturated (e.g. from perspiration), it will lose its adhesive qualities. After use leave the electrodes face up overnight to dry out. At some point the electrodes will become dry. Moisten the adhesive surface with a few drops of water, and apply onto the plastic film overnight. This procedure will give you a few more days of electrode life.
- Replace electrodes onto plastic film after use. If they drop onto the floor debris will adhere to conductive gel rendering the electrodes ineffective.

# 7. Care & Maintenance

## The Unit

- Never expose the stimulator to water. Wipe it off with a damp cloth if necessary.
- Do not use cleaning sprays or alcohol based cleaning solutions

## Batteries

- Check periodically for any discharge from the battery
- Remove battery completely from unit if not in use for any extended period of time (typically one week)
- The battery icon is shown on TENS/NMS side of the display at all times during operation. As the battery discharges, the five bars on the battery icon disappear. Once all bars have disappeared (voltage below 4.4 V), the outline of the battery icon will start to flash. This means that the battery must be replaced.

- Preferably use AA alkaline or rechargeable batteries.

## Lead Wires

- Use only the set of lead wires provided with the device.
- When connecting and disconnecting the lead wires, do so by using the plugs, not the cords
- The lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all.
- Examine lead wires before each treatment for loose connections or damage.
- Avoid stretching and twisting the lead wires.
- Store the lead wires carefully after each use (lead wires are best preserved if left attached to stimulator between sessions).

**Caution: Static electricity may damage this product**

*Note: Only Verity Medical Ltd. or appointed distributors/importers are approved to undertake servicing.*

# 8. Information regarding Electromagnetic compatibility and interference (EMC)

NeuroTrac™ products are designed to produce very low levels of radio frequency (RF) emissions (interference), to be immune from effects of interference produced by other equipment operating in their vicinity and damage due to electrostatic discharge, all when operating in a typical domestic and or clinical environment. They are certified to meet the international EMC standard EN60601-1-2. For more information please refer to the tables 201, 202, 204 and 206.

**Table 201**: Guidance and manufacturer's declaration - electromagnetic emission

The NeuroTrac™ product is intended for use in the electromagnetic environment specified below. The customer or the user of the The NeuroTrac™ product should ensure that it is used in such environment

| Emission test | Compliance | Electromagnetic environment guidance |
|---|---|---|
| RF emission<br>CISPR 11 | Group 1 | The NeuroTrac™ product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment |
| RF emission<br>CISPR 11 | Class B | The NeuroTrac™ product is suitable for use in all establishments , including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Not applicable | |

**Table 202**: Guidance and manufacturer's declaration – electromagnetic immunity

The NeuroTrac™ product is intended for use in the electromagnetic environment specified below. The customer or the user of theNeuroTrac™ product should assure that it is used in such an environment, and that precautions regarding that environment are heeded.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment guidance |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | 6 kV contact<br>±8 kV air | ±6 kV contact<br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

**Table 204**: Guidance and manufacturer's declaration – electromagnetic immunity

The NeuroTrac™ product is intended for use in the electromagnetic environment specified below. The customer or the user of the NeuroTrac™ product should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment guidance |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms 150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the NeuroTrac™product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>d = 1.2 √P 150 kHz to 80 MHz,<br>d = 1.2 √P 80 MHz to 800 MHz<br>d = 2.3 √P 800 MHz to 2.5GHz |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2,5 GHz | 3 V/m 80 MHz to 2,5 GHz | where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a],<br>should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which NeuroTrac™ product is used exceeds the applicable RF compliance level above, the NeuroTrac™ product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NeuroTrac™ product.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Table 206**: Recommended separation distances between portable and mobile RF communications equipment and NeuroTrac™ product

The NeuroTrac™ product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NeuroTrac™ product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NeuroTrac™ product as recommended below, according to the maximum output power of the communications equipment

| **Rated maximum output power of transmitter** W | **Separation distance according to frequency of transmitter** | | |
|---|---|---|---|
| | **150 kHz to 80 MHz** $d = 1.2\sqrt{P}$ | **80 MHz to 800 MHz** $d = \sqrt{1.2}\,P$ | **800 MHz to 2,5 GHz** $d = \sqrt{2.3}\,P$ |
| 0,01 | 0.12 | 0.12 | 0.23 |
| 0,1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# 9. Technical Specification

## General

| | |
|---|---|
| **Number of channels:** | 2 for TENS/NMS and 2 for IFC |
| **Channel isolation:** | Depends upon use of 4 independent transformers. |
| **Output Regulation:** | Constant Current |
| **Waveform:** | **IFC** - Symmetrical square biphasic with zero net DC.<br>**TENS/NMS** - Asymmetrcal, square, biphasic with zero net DC. |
| **Energy source:** | 4 x 1.5V AA non-rechargeable or<br>4 x 1.2V AA rechargeable batteries. |
| **Response to the voltage of the batteries:** | If the voltage goes below 4.4 volts +/- 0.2 the empty battery symbol will flash on and off once every second.<br>If the voltage is below 4.0 volts +/- 0.2 the unit will not turn on. |
| **Open Electrode detect:** | If an open circuit is detected at the output of the Channel 1 and 2 or Channel A and B the output current will be reduced to 0 (for both CH1 and CH2 or CHA and CHB channel). |
| **Size:** | L:152mm, W: 89mm, D: 35mm |
| **Weight:** | 0.3 Kg ( including batteries) |
| **Environmental Specification:** | **Storage and transport**<br>Temp: -10 to +50 degrees Centigrade.<br>Humidity - 0-90%<br><br>**Operating**<br>Temp: +10 to +30 degrees Centigrade.<br>Humidity - 0-90% |

## Interferential Stimulation (IFC)

| | |
|---|---|
| **Carrier Frequency:** | 4000Hz nominal , fixed |
| **Adjustable Frequency:** | 4001-4150Hz nominal, adjustable |
| **Interference Frequency:** | 1-150 Hz , equal to the difference frequency between Carrier and Adjustable frequency. Determined by frequency setting |
| **Output Configuration:** | Quadra polar (4 -electrodes)<br>- Output Channel 1 delivers Carrier frequency<br>- Output Channel 2 delivers Adjustable frequency<br>Interference occurs within tissue, maximal at point of intersection among four electrodes (see the picture on page 28) |
| **Amplitude:** | 0 -50 mA (indication only; actual mA will tend to be less than indicated due to electrode impedance. |
| **Pulse width:** | 125 µS |
| **Treatment time:** | 1 min - 12 hours ( selectable) |

## TENS

| | |
|---|---|
| **Amplitude:** | 0 - 80 mA<br>Indication only; actual mA will tend to be less than indicated due to electrode impedance. |
| **Pulse width:** | 50 - 300 µS - selectable in PC1 (2% accuracy) |
| **Frequency:** | 2 - 200 Hz - selectable in PC1 (2% accuracy). |
| **Modes:** | **Continuous**<br>**Modulated** - 6-second cycle of concurrent width modulation and pulse repetition rate modulation. Width starting at 200 µS and decreasing exponentially to 100 µS in three seconds and then returning back to 200 µS in the next three seconds.<br>**Burst Modulated** -Bursts of 9 pulses 150 Hz at 175 or 200 µS, repeating twice every second. |
| **Treatment time:** | 1 min - 12 hours selectable in PC2 or PC3 |

## NMS

| | |
|---|---|
| **Amplitude:** | 0 -90 mA<br>Indication only; actual mA will tend to be less than indicated due to electrode impedance. |
| **Pulse width:** | 50 - 450 µS - selectable in PC2 or PC3<br>(2% accuracy) |
| **Frequency:** | 2 - 100 Hz - selectable in PC2 or PC3<br>(2% accuracy) |
| **Ramp Up:** | 0.3 - 9.9 sec. Hz - selectable in PC2 or PC3 |
| **Timing of stimulation:** | Synchronous or Alternating selectable in PC2 or PC3 |
| **Treatment time** | 1 min - 1hr 30 min., selectable in PC2 or PC3 |

## Key to symbols used on the Device labeling.

Caution, consult accompanying documents

BF applied part equipment (Body Floating)

This product is manufactured in compliance with the Medical Device Directive MDD93/42/EEC under the supervision of SGS, Notified Body number 0120

Follow instructions for use

## Disposal of the devices

At the end of the product life cycle, do not throw this product into the normal household garbage, but take it to a collection point for the recycling of electronic components

Some product materials can be re-used if you take them to recycling point. By re-using some parts or raw materials from used products you make an important contribution to the protection of the environment . Please contact your local authorities if you need more information about collection points in your area.

Waste Electrical and Electronic Equipment can have potentially harmful effects on the environment.
Incorrect disposal can cause harmful toxins to built up in the air, water and soil and can be harmful to human health.

# 10. Troubleshooting

| Problem | Possible cause | Remedy |
|---|---|---|
| The display does not come on and there is no signal from the unit | Batteries discharged | Replace batteries |
| | Batteries were incorrectly positioned | Remove battery and replace correctly |
| The unit turns on , but does not carry out commands | Lead wires not fully inserted | Remove plug , reinsert |
| | Broken Lead wires | Replace lead wires |
| Battery symbol flashing | The battery voltage is low | Replace the battery |
| Current drops to 0 mA and readjustment to higher than 10mA level is not possible. | Open circuit detected:<br><br>Broken lead wire.<br>Broken electrode wire.<br>Poor skin/electrode contact. | Replace broken accessory<br><br>If the closed circuit is broken, for example if a Lead wire is broken, the current to both channels (TENS/NMS or IFC) switches off automatically. Excessive resistance results in amplitude being dropped to zero and displayed as 0 mA (flashing). Correct the problem by making sure the connection is re-established (new wires, new electrodes, check on skin connection) and restart the programme by setting the amplitude. |

If you cannot find the answer from the above table, please visit our website www.veritymedical.co.uk, select CONTACT US and then select KNOWLEDGE BASE to get the most up to date list of possible solutions.
If you experience a continuous problem and are thinking of returning the product or getting it fixed, please read the warranty section on page 40:
- Contact your Distributor who may be able to guide you through any issues.
- You will need to obtain notice from the Distributor from whom you purchased the unit before returning it to them for replacement or repair (sometimes the returned products are not faulty and there is another reason for it not working, in this situation you might be charged for postage and/or product examination).

# 11. Warranty

Verity Medical Ltd., provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of 2 years from the date of purchase by the Distributor [invoice date from Verity Medical to the appointed Distributor].
If the distributor from whom the product was purchased by the user is satisfied that the product is defective, the user may return the unit directly to this Distributor who will forward it to Verity Medical Ltd. All such returns from the Distributor to Verity Medical must be authorised by Verity Medical Ltd., in advance. The liability of Verity Medical Ltd., under this limited product warranty does not extend to any misuse or abuse such as dropping or immersing the unit in water or other liquid substance or tampering with the unit or normal wear and tear. Any evidence of tampering will nullify this warranty.

**Customer Service**

Any queries should be addressed to:

Verity Medical Ltd.
Unit 7, Upper Slackstead Farm
Farley Lane, Braishfield
Romsey
Hampshire SO51 0QL
United Kingdom

Tel: +44 (0) 1794 367 110
+44 (0) 1794 367 451

Fax: +44 (0) 1794 367 890

Email: sales@veritymedical.co.uk
Web: www.veritymedical.co.uk

This product is manufactured by Verity Medical Ltd., in compliance with the European Union Medical Device Directive MDD93/42/EEC under the supervision of SGS, Notified Body number 0120.

CE 0120

Verity Medical Ltd., is certified by SGS to the following Quality Standards:
ISO 9001:2008, ISO13485:2003.

The Device is not for sale in the USA

**Distributor:**


**Win Health Ltd.**

**Brockhirst, Oxnam Road**

**Jedburgh, Roxburghshire, TD8 6QN**

**Tel.: 01835 864866 / Fax: 01835 863238**

**E-mail: info@win-health.co.uk**

**Website: www.win-health.co.uk**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